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10/809,962	03/26/2004	Clifton A. Alferness	11998.5USC8	7915				
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/809,962
Filing Date: March 26, 2004
Appellant(s): ALFERNESS ET AL.

MAILED
OCT 05 2007
Group 3700

Brian W. Oberst
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/18/2007 appealing from the Office action mailed 9/8/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: the applicant newly argued that German silver is not biocompatible. Muller was added to the rejection of claims 18, 19, 22, 23, 26, 28, 34 and 35 over Field (1,682,119) as an evidentiary reference making a new ground of rejection.

NEW GROUND(S) OF REJECTION

Claims 18, 19, 22, 23, 26, 28, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Field (1,682,119) as evidenced by Muller (3,452,742).

Claims 18, 22, 23, and 28 – metallic envelope –2- is a jacket, both ends of the envelope are open and both ends may be selectively closed. German silver may be used for the jacket and German silver is biocompatible. The applicant newly argues that German silver is not biocompatible. The examiner directs the applicants attention to Muller, 3,452,742 that teaches a vascular spring guide may be made with German silver, column 5, lines 44 through 52, clearly German silver is biocompatible.

The material pattern shown in figure 3 and arranged as shown in figure 1 provides for a jacket having the particular expansion properties as claimed in the functional language set forth in the claims. The claim language does not set any specific size for the jacket only a size relative to the size of an undefined heart, therefore if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims. The shape of the envelope -2- will be determined by what is placed in the envelope further the material pattern allows for the shape to be adjusted. The interconnected rows of hinges provide for expansion and contraction in the circumferential direction without affecting the length of the envelope. Therefore it is the examiner's position that if placed on a heart the expansion properties of Field will be as claimed by the applicant. Further, the applicant's attention is directed to paragraph [0058] of the applicants specification where it is set forth that "Once placed, the jacket's volume and shape are adjusted for the

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jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (FIG. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole." Therefore it is the examiner's position that "shaped" as claimed represents a functional limitation provided for by the construction of Field.

Claim 19 – elongate members form cells as shown in figure 3.

Claim 26 – the members may be German silver.

Claims 34 and 35 – the jacket as taught by Field has open ends that are selectively closed by elements –3-. Before either end is closed the jacket has two open ends and after one end is closed and before the second end is closed the jacket would have one open end and one closed end.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,839,842	Wanat et al	11-1998
1,682,119	Field	10-1925
3,452,742	Muller	6-1966

2,376,442

Mehler

7-1943

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18, 19, 22, 23, 28 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Wanat et al (5,839,842). The examiner is taking only jacket –2- of the entire kit of Wanat et al to meet the claims as set forth below.

Claims 18, 23, and 28 – element –2- forms a jacket, the jacket has an open end shown at –6-, and the jacket may be formed from polyethylene, a biocompatible material. The diamond pattern allows for differential expansion of the jacket with the diamond pattern

oriented as shown in figure 1. It is the examiner's position that the jacket of Wanat et al is with the diamond pattern oriented as shown is inherently capable of performing the other functions set forth in the functional language of the claim. The claim language does not set any specific size for the jacket only a size relative to the size of an undefined heart, therefore if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims. The claim was amended to include "shaped", it is the examiner's position that tubular mesh bags assume the shape of whatever is placed inside of them therefore meets the limitation of being shaped to snugly conform to an external geometry of the heart. Further, the applicant's attention is directed to paragraph [0058] of the applicants specification where it is set forth that "Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (FIG. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole." Therefore it is the examiner's position that "shaped" as claimed represents a functional limitation provided for by the knit construction. It is also the examiner's position that the mesh structure of Wanat provides the same functional limitation.

Claim 19 – the examiner is taking each leg of the diamond pattern as elongated members.

Claim 22 – the jacket is configured to constrain at least a lower portion of the heart.

Claim 35 – the jacket includes a closed end.

Claims 18, 19, 22, 23, 25, 28, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehler(2,376,442).

Claims 18, 23, and 28 – element –10- forms a jacket, the jacket may be knotted at –11- and –12- therefore either or both ends may be open or closed. The diamond pattern allows for differential expansion of the jacket with the diamond pattern oriented as shown in figure 1 which is inherently capable of performing the other functions set forth in the functional language of the claim. The claim language does not set any specific size for the jacket only a size relative to the size of an undefined heart, therefore if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims. The specific material to make the netting is not set forth, however it appears that the material would be the same as used for other fish netting devices as described in column 1. Matheson(4,466,331) lists a variety of materials well known in the net making art used for making fish nets, column 1 lines 53-59.

Polyethylene is a well-known material in the net-making arts, therefore it is clear to one of ordinary skill in the art in the absence of any specific guidance in Mehler itself that polyethylene may be selected to make the net of Mehler. The examiner is taking polyethylene to be a biocompatible material. The specific design of the mesh pattern determines expansion and contraction in the circumferential direction and longitudinal direction. Therefore it is the examiner's position that if placed on a heart the expansion

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properties of Mehler et al will be as claimed by the applicant. Further, the applicant's attention is directed to paragraph [0058] of the applicants specification where it is set forth that "Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess material of the jacket 10 can be gathered and sutured S" (FIG. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole." Therefore it is the examiner's position that "shaped" as claimed represents a functional limitation provided for by the construction of Mehler.

Claim 19 – the examiner is taking each leg of the diamond pattern as elongated members.

Claim 22 – the jacket is configured to constrain at least a lower portion of the heart.

Claim 25 a plurality of fibers are used, applicant's attention is invited to Figure 2.

Claim 34 – the ends –11- and –12- are open before they are closed.

Claim 35 – the jacket includes a closed end –11- or –12-.

NEW GROUND(S) OF REJECTION

Claims 18, 19, 22, 23, 26, 28, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Field (1,682,119) as evidenced by Muller (3,452,742).

Claims 18, 22, 23, and 28 – metallic envelope –2- is a jacket, both ends of the envelope are open and both ends may be selectively closed. German silver may be used for the jacket and German silver is biocompatible. The applicant newly argues that German silver is not biocompatible. The examiner directs the applicants attention to Muller, 3,452,742 that teaches a vascular spring guide may be made with German silver, column 5, lines 44 through 52, clearly German silver is biocompatible.

The material pattern shown in figure 3 and arranged as shown in figure 1 provides for a jacket having the particular expansion properties as claimed in the functional language set forth in the claims. The claim language does not set any specific size for the jacket only a size relative to the size of an undefined heart, therefore if one selects a heart of the appropriate size any size net would meet the relative limitations set forth in the claims. The shape of the envelope -2- will be determined by what is placed in the envelope further the material pattern allows for the shape to be adjusted. The interconnected rows of hinges provide for expansion and contraction in the circumferential direction without affecting the length of the envelope. Therefore it is the examiner's position that if placed on a heart the expansion properties of Field will be as claimed by the applicant. Further, the applicant's attention is directed to paragraph [0058] of the applicants specification where it is set forth that "Once placed, the jacket's volume and shape are adjusted for the jacket 10 to snugly conform to the external geometry of the heart H during diastole. Such sizing is easily accomplished due to the knit construction of the jacket 10. For example, excess

material of the jacket 10 can be gathered and sutured S" (FIG. 5) to reduce the volume of the jacket 10 and conform the jacket 10 to the shape of the heart H during diastole." Therefore it is the examiner's position that "shaped" as claimed represents a functional limitation provided for by the construction of Field.

Claim 19 – elongate members form cells as shown in figure 3.

Claim 26 – the members may be German silver.

Claims 34 and 35 – the jacket as taught by Field has open ends that are selectively closed by elements -3-. Before either end is closed the jacket has two open ends and after one end is closed and before the second end is closed the jacket would have one open end and one closed end.

(10) WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Claims 18, 19, 22, 23, 28 and 34 rejected under 35 U.S.C. 102(b) as being anticipated by Mercer et al (3,551,543) has been withdrawn.

(11) Response to Argument

Regarding Ground of Rejection 1 Arguments:

The applicant argues that claim 18 requires a jacket having a specific size and shape so as to snugly conform to the external geometry of the heart and that the device of Wanat does not set forth such a structure.

The examiner would like to first address heart size. The claim does not set forth any specific heart size, therefore a reasonable interpretation of the claim is that any size suitable for any heart is covered. The size of the heart in a human is generally the size of a human hand in the shape of a fist. An infant heart is very small, about the size of a walnut, while the adult heart is quit a bit larger, about the size of a grapefruit. Further, the claim does not limit the device for use with a human heart therefore the device may be sized to fit a mouse heart, about the size of a pea or an adult blue whale which has a heart roughly the size of a Volkswagen beetle. Therefore, the Examiner believes that the size of the heart as claimed ranges from about the size of a pea to about the size of a Volkswagen beetle. The mesh bag of Wanat is sized to enclose a heart up to its maximum size which is clearly smaller than a Volkswagen beetle.

The applicant argues that Wanat shows gaps and slack between the pouch and the contents in the figure. The examiner agrees however the spaces and gaps depend on the objects placed in the bag, if an appropriately sized heart is placed in the bag the bag will "snugly conform" to at least a portion of the heart.

With respect to "snugly conform", the mesh bag of Wanat will have an at rest size where no forces are applied to deform the normal shape and size of the mesh. The bag will also have a maximum size at which the mesh is expanded to its maximum size. When a heart having a size greater than the at rest size and smaller than the maximum

size is placed in the bag, the bag will be expanded and inherently “snugly conform” to an external geometry of the object. The claim language is very broad in that the jacket needs to only snugly conform to “an external geometry of said heart”. The jacket need not “snugly conform” to the entire external geometry of the heart. Therefore, if an appropriately sized heart is selected the bag will “snugly conform” to at least a portion of the heart. The mesh construction inherently provides shape conforming properties.

With respect to “constrain circumferential expansion” the applicant argues that the examiner completely ignored this limitation. The examiner disagrees because the bag of Wanat has a maximum expanded size, if a heart is selected that fits into the bag during systole but has a size at diastole which is larger than the maximum size of the mesh bag the mesh bag will constrain the “circumferential expansion” of the heart. As shown above the bag would clearly have a maximum size smaller than a Volkswagen beetle. Therefore, the bag is clearly structurally capable of constraining the circumferential expansion of the heart.

The applicant goes on to argue that reliance on paragraph [0058] is misplaced and that an embodiment including adjusting the size and shape of the jacket after placement is irrelevant. The examiner disagrees, because “shaped and sized” is interpreted in view of this embodiment. A jacket according to this embodiment is large enough to be placed over the heart and then requires adjustment by gathering and suturing to “snugly conform” to the heart. If the jacket is gathered and sutured to snugly fit the AV groove the jacket could not be placed on the heart over the apex of the heart because the AV groove is considerably smaller than the maximum circumference of the

heart. The mesh bag of Wanat is clearly sized and shaped of being placed over an appropriately sized heart as set forth above and clearly structurally capable of being gathered and sutured to snugly conform to the heart.

The applicant further argues that the Wanat patent fails to disclose and cannot disclose biocompatible material that exhibits an amount of expansion in response to a force applied by the heart in one direction that is different from the expansion in a second direction. In response, mesh clearly forms a material exhibiting differential expansion, the bag will clearly have different expansional properties along the lines forming the diamonds and across the diamonds themselves. This is an inherent property of mesh. The diamonds are oriented such that the diamond may expand more in the longitudinal direction than in the circumferential direction in response to a force applied by the heart in a longitudinal direction. The claim does not require the force to be applied in any particular direction.

Regarding Ground of Rejection 2 Arguments:

With respect to Field the applicant argues that Field clearly has nothing to do with a jacket for placement on and treating a disease of the heart and cannot anticipate the rejected claims. The Examiner disagrees in that the field of use has no bearing on an anticipation rejection based on the structure of the device.

The applicant argues that Field fails to disclose or suggest a jacket sized and shaped to snugly conform to an external geometry of the heart as recited in claim 18, regardless of the size of the heart. As set forth above it is the examiner's position that the size of a heart ranges from about the size of a pea to the size of a Volkswagen beetle. The envelope of Field as shown snugly conforms to the soap chips placed therein and therefore, would snugly conform to an appropriately sized heart placed therein. It is the examiners position that the envelope of Field would have an at rest size and a maximum expanded size. The expansion created by the expanding/flexing the hinges of the sinusoidal shape of metallic material. The device is also sized to gripped and used by an adult human. Therefore, the Examiner believes it is clear that a heart the size between a pea and a Volkswagen beetle may be placed inside the envelope.

When a heart having a size greater than the at rest size and smaller than the maximum size is placed in the bag, the bag will be expanded and inherently "snugly conform" to an external geometry of the objected due to the springiness of the material. The claim language is very broad in that the jacket needs to only snugly conform to "an external geometry of said heart". The jacket need not "snugly conform" to the entire external geometry of the heart. Therefore, if an appropriately sized heart is selected the envelope will "snugly conform" to at least a portion of the heart. The envelope springiness provides shape conforming properties.

With respect to "constrain circumferential expansion" the applicant argues that the examiner completely ignored this limitation. The examiner disagrees because the envelope has a maximum expanded size, if a heart is selected that fits into the envelope during systole but has a size at diastole which is larger than the maximum size of the envelope, the envelope will constrain the "circumferential expansion" of the heart. As shown above the envelope clearly has a maximum size smaller than a Volkswagen beetle.

With respect to the differential expansion properties, because the plurality of rows are not rigidly connected but merely slide over each other they clearly would have different amount of expansion than the amount of circumferential expansion due to the same force. The claim does not require any specific direction of the force applied to the envelope by the heart. It is the Examiner's position that a longitudinal force applied to the envelope from the heart would longitudinally expand the envelope while causing no circumferential expansion. The structure of the envelope clearly inherently provides these properties. The applicant argues that the soap chips do not expand so the characteristics of the disclosed envelope would appear to be irrelevant to the teaching of the Field patent. The properties of the envelope, while not required for the use with soap chips are clearly still a property of the envelope and not irrelevant. The orientation of Field placed on the heart is clearly apparent that the envelope would be opened at least at one end and slid over the heart, further, both ends could remain open.

The applicant further argues German silver is not a "biocompatible material" as claimed. The applicant has not provided any evidence to show German silver is not a biocompatible material. It is the examiner's position that German silver is a biocompatible material and points to Muller, 3,452,742 that teaches a vascular spring guide may be made with German silver, column 5, lines 44 through 52.

Finally the applicant argues that "scraping edges" render the mesh envelope wholly unsuitable as a jacket sized and shaped to snugly conform to an external geometry of the heart. While the scraping edges are used to clean surfaces the edges are not intended to cut or damage the surface of the material they are used on further, the envelope is flexible, and formed of a relatively soft metal and the device is used by hand without causing injury to the user and therefore is suitable for use as an implant.

Regarding Ground of Rejection 4 Arguments:

The applicant argues that Mehler teaches a device having a substantially uniform diameter and will not necessarily satisfy the requirements of snugly conforming to the external geometry of the heart to constrain expansion during diastole and provide unimpeded contraction of the heart.

As set forth above it is the examiner's position that there is a wide variety of heart sizes and at least a small heart would fit in the tubular netting. The netting inherently has an at rest size and a maximum expanded size. If a heart having a size larger than the at rest size and smaller than the maximum size is positioned within the

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netting, the netting would inherently snugly conform to at least a portion of the external geometry of the heart. Again the claim does not require that the jacket snugly conform to the entire external geometry of the heart. Further, if a heart is selected that fits into the netting during systole but has a size at diastole which is larger than the maximum size of the netting, the netting will constrain the "circumferential expansion" of the heart. As shown above the netting clearly has a maximum size smaller than a Volkswagen beetle.

Regarding the differential expansion properties of the netting, if a force is applied in the longitudinal direction the netting will expand in the first direction, longitudinal direction, a greater amount than the expansion in the second direction, the circumferential direction (traverse direction). Further, the examiner's position regarding the netting being more readily expandable in the longitudinal direction than in the traverse direction because when a force is applied in the longitudinal direction the netting is more readily expandable in the longitudinal dimension and the traverse direction will either remain the same or be reduced in size as is the inherent property of such a netting.

The examiner believes that paragraph [0058] in the specification sets forth a jacket that is placed around the heart and the shape is changed by gathering and suturing the jacket so the jacket will snugly conform to an external geometry of the heart. The rejected claims do not include sutures or means for changing the shape of

the device. Further, if the claim language "shaped and configured" included the gathering and suturing the jacket, the jacket would not be able to be placed on the heart because the opening of the jacket placed at the AV groove would have a smaller circumference than the largest circumference of the heart and would not be able to be slipped over the heart. Therefore, it is the position of the examiner that the current claims include a jacket that sized to be slipped over the heart and then gathered and sutured to snugly conform to an external geometry of the heart and the devices set forth by Mehler and Wanat are capable of being used in such a manner.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of

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rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

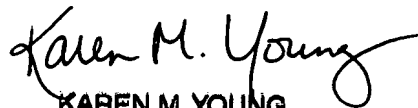
Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/Samuel Gilbert/

Samuel Gilbert
Primary Examiner
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A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:



KAREN M. YOUNG
DIRECTOR
TECHNOLOGY CENTER 3700

Conferees:



Charles Marmor
SPE 3735



Janet Baxter
TQAS 3700